REMARKS

Reconsideration and withdrawal of the rejections of and objections to the application are respectfully requested in view of the amendments and remarks herewith, which place the application into condition for allowance, or into better condition for appeal.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1, 16-19 and 21-30 are pending. Claim 1 is amended, and new claim 30 added, without prejudice.

No new matter is added.

It is submitted that these claims are patentably distinct from the prior art, and that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims, and the remarks made herein, are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support for the amended recitation in claim 1, and for new claim 30, is found throughout the specification.

II. 35 U.S.C. §102 REJECTION

Claims 1, 18-23, 25 and 29 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent No. 5,965,155 (the " '155 patent"). The rejection is traversed.

The instant invention is directed to, *inter alia*, a transdermal system for the delivery of clonidine consisting essentially of a pressure-sensitive contact adhesive layer comprising clonidine and a copolymer, wherein said copolymer consists of 2-ethylhexyl acrylate and vinyl

acetate; a covering; and on a side opposite from the covering, a removable support that temporarily covers the contact adhesive layer (claim 1). The instant invention is also directed to a transdermal system for the delivery of clonidine consisting essentially of a pressure-sensitive contact adhesive layer comprising clonidine, acrylate and a copolymer, wherein said copolymer comprises 2-ethylhexyl acrylate and vinyl acetate; a covering; and on a side opposite from the covering, a removable support that temporarily covers the contact adhesive layer, wherein the concentration of said clonidine is in a range of from 0.1 to 20% by weight (claim 30). The claimed elements are absent from the '155 patent.

It is respectfully pointed out that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.,* 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. *See Chester v. Miller,* 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. *See In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Applying the law to the instant facts, the '155 patent does not disclose, suggest or enable Applicants' invention. More specifically, the '155 patent fails to disclose, suggest or enable either a transdermal system for the delivery of clonidine consisting essentially of a pressure-sensitive contact adhesive layer comprising clonidine and a copolymer, wherein said copolymer consists of 2-ethylhexyl acrylate and vinyl acetate; a covering; and on a side opposite from the covering, a removable support that temporarily covers the contact adhesive layer (claim 1); **or** a transdermal system for the delivery of clonidine consisting essentially of a pressure-sensitive contact adhesive layer comprising clonidine, acrylate and a copolymer, wherein said copolymer

comprises 2-ethylhexyl acrylate and vinyl acetate; a covering; and on a side opposite from the covering, a removable support that temporarily covers the contact adhesive layer, wherein the concentration of said clonidine is in a range of from 0.1 to 20% by weight (claim 30). Thus, as the claimed elements are absent from the '155 patent, and as the '155 patent does not enable the instant invention, the rejection must fail as a matter of law.

Consequently, reconsideration and withdrawal of the Section 102 rejection are warranted, and such actions are respectfully requested.

III. 35 U.S.C. §103 REJECTION

Claims 1, 16-19 and 21-29 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the '155 patent. The rejection is traversed. The '155 patent fails to teach, suggest or motivate a skilled artisan to practice the instantly claimed invention.

It is respectfully asserted that it is well-settled that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further, "obvious to try" is not the standard under 35 U.S.C. §103. *In re Fine,* 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification." Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, **both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure**. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

Applying the law to the instant facts, the '155 patent fails to teach or suggest either a transdermal system for the delivery of clonidine consisting essentially of a pressure-sensitive contact adhesive layer comprising clonidine and a copolymer, wherein said copolymer consists of 2-ethylhexyl acrylate and vinyl acetate; a covering; and on a side opposite from the covering, a removable support that temporarily covers the contact adhesive layer (claim 1); **or** a transdermal system for the delivery of clonidine consisting essentially of a pressure-sensitive contact adhesive layer comprising clonidine, acrylate and a copolymer, wherein said copolymer comprises 2-ethylhexyl acrylate and vinyl acetate; a covering; and on a side opposite from the covering, a removable support that temporarily covers the contact adhesive layer, wherein the concentration of said clonidine is in a range of from 0.1 to 20% by weight (claim 30).

The '155 patent relates **exclusively** to a pentetrazole (6,7,8,9-tetrahydro-5H-tetrazole(1,5-a)azepine) transdermal system, **not** to a clonidine transdermal system. Nowhere in the '155 patent is there exemplification of, for example, a clonidine patch or a clonidine patch having a concentration of clonidine at a range of from 0.1 to 20% by weight. The portion of the '155 patent cited by the Office Action as allegedly teaching a transdermal clonidine patch is, **at most**, no more than a mere wish list of what the '155 patent may have intended to, *arguendo*, accomplish and does not render obvious the instantly claimed invention.

Thus, the only expectation of success is found in applicants' specification as nowhere in the '155 patent is there any teaching that would lead a skilled artisan to practice a transdermal patch for the delivery of clonidine. Again, the Federal Circuit in *In re Fine* was very clear that "obvious to try" is not the standard on which an obviousness rejection should be based. And as "obvious to try" would be the only standard that would lend the instant rejection any credibility, the rejections must fail as a matter of law.

Consequently, reconsideration and withdrawal of the Section 103 rejections are respectfully requested.

As this paper is being submitted within the three-month term for reply set by the July 1, 2002 Office Action, no fee is believed to be due. In the event, however, a fee is required for the consideration of this paper, the Assistant Commissioner is authorized to charge such fee, or credit any overpayment, to Deposit Account 50-0320.

CONCLUSION

In view of the remarks and amendments herewith and those of record, the application is in condition for allowance or in better condition for appeal. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,

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VERSION TO SHOW CHANGES MADE

1. (Amended Twice) A transdermal system for the delivery of clonidine consisting essentially of:

a pressure-sensitive contact adhesive layer comprising clonidine[, acrylate] and a copolymer, wherein said copolymer [comprises] consists of 2-ethylhexyl acrylate and vinyl acetate;

a covering; and

on a side opposite from the covering, a removable support that temporarily covers the contact adhesive layer.